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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,824	11/07/2001	Fernand Labrie	P/1259-636	4181

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,824	LABRIE, FERNAND	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 13-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/30/06, 9/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/30/2006 has been entered.

Claim(s) 1-28 are pending. Claim(s) 7-12 have been withdrawn. Claim(s) 1-2 have been amended. Claim(s) 1-6, 13-28 are examined herein.

Applicant's arguments have been fully considered and found not persuasive. All the rejections are maintained for reasons of record and repeated below for Applicant's convenience.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 21-28 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular selective estrogen receptor modulator (SERM) compounds having the formula in claims 13-20 herein and the particular estrogens in claims 20-21, further in combination with the particular additional agent such as DHEA in the claimed methods herein, does not reasonably provide enablement for any selective estrogen receptor modulator and any estrogens and any androgenic agents, encompassed by the claims herein, for the same reasons of record in the previous Office Action November 18, 2004.

The recitations, "one selective estrogen receptor modulator" "one estrogen", and "an androgenic agent" are seen to be merely functional language.

Even regarding the recitation for compounds in claims 4-5, one skilled in the art

would clearly recognize that the recitation would encompass numerous compounds containing various structurally different substituents.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQZd 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to the methods for the therapeutic treatments for menopausal patients.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the broadest claims (i.e., claims 1-2) reads on any “selective estrogen receptor modulator” and "estrogen" and any "androgenic agent" encompassed by the claims herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in University of California v. Eli Lilly and Co. 43 USPQZd 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outine goal appellants hope the

recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "(A) written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at l405 (emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case, "one selective estrogen receptor modulator" "one estrogen" and "an androgenic agent" recited in the instant claims are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. However, the specification merely provides those particular compounds for each kind of functional compounds for the composition in claims.

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (General Electric Company v. Wabash Appliance Corporation et al. 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly

unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in University of California v. Eli Lilly and Co. Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (e.g., a human) the combination of any compounds represented by "one selective estrogen receptor modulator" "one estrogen" and "an androgenic agent" See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9* ed 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough

knowledge of the intended and possible effects of drugs that are prescribed" and that 'The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would not be able to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional properties in the pharmaceutical compositions herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

Further, any compounds represented by "one selective estrogen receptor modulator" "one estrogen" and "an androgenic agent" may reasonably encompass those known and unknown three classes functional compounds as of the instant filing date, especially those future known selective estrogen receptor modulators and estrogens and androgenic agent. As a result, additional or future research to establish or verify their usefulness must be required.

Therefore, to practice the claimed invention herein, a person of skill in the art would have to exercise undue experimentation to test all compounds encompassed in the instant claims.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only those particular compound for each kind of functional

compounds employed in the composition herein is disclosed in the specification.

Moreover, it is noted that the specification merely provides the testing of two particular SERMS (i.e., EM-652 and EM-800) in working examples of the instant specification.

Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the compounds in the claimed composition.

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitatinq one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, the case University of California. v. Eli Lllly and Co. (CAFC, 1997) and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be administered to a host, with no assurance of success.

Response to Arguments

Applicant argues that the enablement rejections should be withdrawn because the claims have been amended to now recite the specific definition of SERMs set forth on page 10, lines 13-17 of the specification. This is not persuasive because the new limitations merely recite the specific function of SERMs. The enablement rejection is based on the fact that the disclosure is enabled for only SERM compounds having formula in claims 13-21, and not ALL SERM compounds, estrogens, and androgenic agents. The rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 23-28 are rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the same reasons of record in the previous Office Action November 18, 2004.

The recitations, "derivative" and "derivatives" in the claims render claims 1-6 and 23-28 indefinite. The recitations, "derivative" and "derivatives" are not defined in the specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to "derivative" and "derivatives" in the claim. Therefore, the scope of claim is indefinite as to the composition encompassed thereby.

Response to Arguments

Applicant has not addressed this rejection in the response; therefore, it is maintained for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-6 and 13-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Labrie (5,362,720), and Labrie et al. (WO 96/26201), and Applicant's admission regarding the prior art in the specification at 2 lines 3-4, for the same reasons of record in the previous Office Action November 18, 2004.

Labrie (5,362,720) teaches that estrogens such as l7l-estradiol are well known to be used in estrogen therapy in menopausal women. However, estrogens are known

to induce estrogen-dependent diseases such as breast cancer. Labrie also discloses that androgenic compounds or androgenic steroids are useful in methods of treating or preventing estrogen-dependent diseases such as breast cancer. See abstract, col.1 line 35-38, col.4 lines 45-48, col.10, and claims 1-30.

Labrie et al. (WO 96/26201) discloses that the particular SERM, EM-652 (the instant elected species) or its pharmaceutically acceptable salts such as EM-652.HCl, have anti-estrogen activities and are therefore useful in methods of treating estrogen sensitive or estrogen-dependent diseases such as breast cancer, which is known estrogen-induced effects. See abstract, page 1, page 6-8, 10, and 19-21, and claims 11-12.

Applicant's admission regarding the prior art in the specification at 2 lines 3-4 teaches that Hormone Replace Therapy (e.g., administration of estrogens) is known to be useful in treatment of menopausal symptoms.

The prior art does not expressly disclose the employment of the combination of an estrogen such as l7β-estradiol and the particular SERM, EM-652.HCl, or maybe further combining an androgenic compound in a method of reducing or eliminating the incidence of menopausal symptoms.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ of the combination of an estrogen such as l7β-estradiol and the particular SERM, EM-652.HCl, or to further combine an androgenic compound in a method of reducing or eliminating the incidence of menopausal symptoms.

One having ordinary skill in the ad at the time the invention was made would

have been motivated to employ the combination of an estrogen such as l7β-estradiol and the particular SERM, EM-652.HCl, or to further combine an androgenic compound in a method of reducing or eliminating the incidence of menopausal symptoms, since estrogens such as l7β-estradiol is well known in the art to be used in estrogen therapy or Hormone Replace Therapy in menopausal women for reducing or eliminating the incidence of menopausal symptoms.

Moreover, l7β-estradiol in combination with androgenic compounds or androgenic steroids is known to be capable to inhibiting breast tumor or cancer growth, and are therefore useful in methods of treating estrogen-dependent diseases, e.g., breast cancer according to Labrie. Fudher, the padicular SERM, EM-652.HCl, is known to be in methods of treating estrogen-dependent diseases. Therefore, one of ordinary skill in the art would have reasonably expected that combining an estrogen such as l7p-estradiol and the particular SERM, EM-652.HCl, or further combining an androgenic compound would be useful in reducing or eliminating the incidence of menopausal symptoms, while reducing the risk of or treating estrogen-dependent diseases such as breast cancer induced by estrogens during estrogen therapy in menopausal women for reducing or eliminating the incidence of menopausal symptoms, since each of components herein is known to be useful in the same treatment, i.e., treating estrogen-dependent diseases.

Since all active composition components herein are known to useful to reduce or treat estrogen-dependent diseases, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same

purpose. At least additive therapeutic effects would have been reasonably expected. See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Labrie (5,362,720), and Labrie (5,780,460, PTO-892), and Labrie et al. (WO 96/26201), and Applicant's admission regarding the prior art in the specification at 2 lines 3-4 for the same reasons of record in the previous Office Action dated November 18, 2004.

Labrie (5,36),720) teaches that estrogens such as l7β-estradiol are well known to be used in estrogen therapy in menopausal women. However, estrogens are known to induce estrogen-dependent diseases such as breast cancer. Labrie also disdoses that androgenic compounds or androgenic steroids are useful in methods of treating or preventing estrogen-dependent diseases such as breast cancer. See abstract, col.1 line 35-38, col.4 lines 45-48, col.10, and claims 1-30.

Labrie (5,780,460) discloses that sex steroid precursors such as DEHA alone or in combination with an estrogen are useful in method of reducing or eliminating the incidence of menopausal symptoms, e.g., vaginal atrophy and diminished libido, and also useful in methods of treating or preventing estrogen-dependent diseases such as breast cancer. See abstract, col. 1-2, col.3 lines 44-55, and claims 1-2.

Labrie et al. WO 96/26201) discloses that the particular SERM, EM-652 (the instant elected species) or its pharmaceutically acceptable salts such as EM-652.HCl, have anti-estrogen activities and are therefore useful in methods of treating estrogen

sensitive or estrogen-dependent diseases such as breast cancer, which is known estrogen-induced effects. See abstract, page 1, page 6-8, 10, and 19-21, and claims 11-12 .

Applicant's admission regarding the prior ad in the specification at 2 lines 3-4 teaches that Hormone Replace Therapy (e.g., administration of estrogens) is known to be useful in treatment of menopausal symptoms.

The prior art does not expressly disclose the employment of the combination of an estrogen such as l7β-estradiol and the particular SERM, EM-652.HCl, and DHEA in a method of reducing or eliminating the incidence of menopausal symptoms.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ of the combination of an estrogen such as l7β-estradiol and the particular SERM, EM-652.HCl, and DHEA in a method of reducing or eliminating the incidence of menopausal symptoms.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the combination of an estrogen such as l7β-estradiol and the particular SERM, EM-652.HCl, and DHEA in a method of reducing or eliminating the incidence of menopausal symptoms, since estrogens such as l7β-estradiol are well known in the art to be used in estrogen therapy or Hormone Replace Therapy in menopausal women for reducing or eliminating the incidence of menopausal symptoms. Moreover, sex steroid precursors such as DEHA alone or in combination with an estrogen (e.g., l7β-estradiol) is known to be useful in method of reducing or eliminating the incidence of menopausal symptoms, and also useful in methods of

treating or preventing estrogen-dependent diseases such as breast cancer according to Labrie. Androgenic compounds are also known to be useful in methods of treating estrogen-dependent diseases. Further, the particular SERM, EM-652.HCl, is known to be in methods of treating estrogen-dependent diseases.

Therefore, one of ordinary skill in the art would have reasonably expected that combining an estrogen such as l7β-estradiol and the particular SERM, EM-652.HCl, and DHEA, or further combining an androgenic compound would be useful in reducing or eliminating the incidence of menopausal symptoms, while reducing the risk of or treating estrogen-dependent diseases such as breast cancer induced by estrogens during estrogen therapy in menopausal women for reducing or eliminating the incidence of menopausal symptoms, since each of components herein is known to be useful in the same treatment, i.e., treating estrogen-dependent diseases.

Since all active composition components herein are known to useful to reduce or treat estrogen-dependent diseases, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Response to Arguments

Applicant argues that EM-652.HCl is disclosed in the WO 96/26201 reference to be an estrogen receptor antagonist, which is in direct contradiction with the Applicant's present specification, which teaches that such antagonistic activity does not occur.

This is found not persuasive because the Examiner will not read any limitations from the specification into the claims. The court ruled that limitations, not present in the claims, were improperly imported from the specification. See also In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) ("Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their broadest reasonable interpretation'." 710 F.2d at 802, 218 USPQ at 292 (quoting In re Okuzawa, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original).

The rejection is maintained for reasons of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, and 13-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 14 of U.S. Patent No. 6,670,346.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of treating or reducing the risk of breast cancer and osteoporosis in a patient in need of said treatment comprising the same SERM or structurally substantially similar SERM herein and DHEA. The patent also discloses patients therein could also undergo Hormone Replace Therapy (e.g., administration of estrogens). It is noted that the transitional phrases "comprising" is employed in the method of the patent. Note that the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03.

The claim of the instant application is drawn to methods of reducing or eliminating the incidence of menopausal symptoms comprising administering the same SERM, estrogen and DHEA to menopausal patients. As discussed above, the patients in the patent are seen to encompass the menopausal patients in the instant application who is well known to have breast cancer and osteoporosis.

Thus, the instant claims 1-6, and 13-28 are seen to be obvious over the claims 1 and 14 of U.S. Patent No. 6,670,346.

Claims 1-6, and 13-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 8-1 1, and 19-28 of U.S. Patent No. 6,465,445.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of treating or reducing the risk of breast cancer and osteoporosis in a patient in need of said treatment comprising the same SERM or structurally substantially similar SERM herein and DHEA. The patent also discloses patients therein could also undergo Hormone Replace Therapy (e.g., administration of estrogens). It is noted that the transitional phrases "comprising" is employed in the method of the patent. Note that the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03.

The claim of the instant application is drawn to methods of reducing or eliminating the incidence of menopausal symptoms comprising administering the same SERM, estrogen and DHEA to menopausal patients. As discussed above, the patients in the patent are seen to encompass the menopausal patients in the instant application who is well known to have breast cancer and osteoporosis.

Thus, the instant claims 1-6, and 13-28 are seen to be obvious over the claims 1-2, 8-11, and 19-28 of U.S. Patent No. 6,465,445.

Response to Arguments

Applicant argues that DHEA is an optional third agent in addition to estrogen, not in lieu of estrogen. Thus, it is the requirement of estrogen that is not suggested by the cited reference. This is not persuasive because the cited reference uses the transitional term "comprising" which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03. Furthermore, the said

treatment disclosed in the cited reference comprises the same SERM or structurally substantially similar SERM herein and DHEA. The patent also discloses patients therein could also undergo Hormone Replace Therapy (e.g. administration of estrogens). The rejection is maintained for reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER